

Notice of Allowability	Application No.	Applicant(s)	
	10/809,816	LI ET AL.	
	Examiner	Art Unit	
	William W. Moore	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Amendment filed 19 October 2005.
2. ☒ The allowed claim(s) is/are 1,2 and 21-30.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>26 March 2004</u> | 7. <input type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

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ALLOWANCE

Priority

This application enjoys the priority of the 26 March 2004 United States filing date.

Information Disclosure Statement

Applicant's Information Disclosure Statement [IDS] filed with the application on 26 March 2004 is hereby acknowledged.

Election

Applicant's election without traverse of the invention of Group I in the reply filed 19 October 2005 is acknowledged, wherein claims are drawn to a cathepsin S protease and compositions comprising same.

Preliminary Amendment

Applicant's Preliminary Amendment filed with the reply 19 October 2005 has been entered, canceling claims 3-20, amending claims 1 and 2 drawn to an isolated Cynomologous cathepsin S protease, and adding new claims 21-30 also drawn to the invention of Group I. Claims 1, 2, and 21-30 remaining in the application are allowed in view of the following examiner's amendment.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Rewrite claims 25-30 thus:

25. (Amended) A composition comprising the polypeptide of claim 1, ~~and a carrier.~~
26. (Amended) A composition comprising the polypeptide of claim 2, ~~and a carrier.~~
27. (Amended) A composition comprising the polypeptide of claim 21, ~~and a carrier.~~

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28. (Amended) A composition comprising the polypeptide of claim 22 ~~and a carrier.~~

29. (Amended) A composition comprising the polypeptide of claim 23 ~~and a carrier.~~

30. (Amended) A composition comprising the polypeptide of claim 24 ~~and a carrier.~~

Authorization for this examiner's amendment was given in a telephone interview with Mr. Justin D. Karjala on 28 November 2005.

The following is an examiner's statement of reasons for allowance:

The mammalian cathepsin S proteases have a well-known utility and page 55 of the specification discloses a specific peptide substrate for the cathepsin S protease of the claims. The above examiner's amendment removes a term not associated with the cathepsin S protease in the originally-filed claims or in the specification. The disclosure of compositions of claims 25-30 comprising proteases of claims 1, 2, and 21-24 is inherent in the specification. Neither the amended claims 1 and 2 nor the new claims 21-30 present any issues of enablement or written description and the allowed claims provide a definite description of the intended subject matter. The new claims 21 and 22 of the preliminary amendment filed 19 October 2005 permit amino acid sequence alteration at as many as three amino acid positions within SEQ ID NO:2 in describing proteases either consisting of or comprising an amino acid sequence 99% identical to SEQ ID NO:2 herein, but the closest prior art teaches the amino acid sequence of a human cathepsin S protease that shares 97% identity with SEQ ID NO:2 herein. See, e.g., the US Patents of Hastings et al., and Abdel-Meguid et al., made of record herewith and cited on the accompanying PTO Form-892. An altered human cathepsin S disclosed in the US Pre-Grant Publication of Lamers et al., made of record herewith, shares 96.8% identity with SEQ ID NO:2 herein. A human protease designated "cathepsin O2" has an amino acid sequence that shares 96.6% identity with SEQ ID NO:2 herein. See the US Patents of Bromme et al., made of record herewith and cited

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on the accompanying PTO Form-892. Thus the prior art does not teach or suggest the subject matter described by claims 1, 2, and 21-30 allowed herewith.

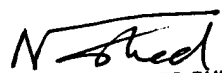
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Dr. Kathleen Kerr, can be reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

William W. Moore
28 November 2005


NASHAAT T. NASHED PHD.
PRIMARY EXAMINER